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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JONATHAN S. STINSON

Appeal 2009-004199
Application 10/672,891
Technology Center 1700

Decided: October 20, 2009

Before CATHERINE Q. TIMM, BEVERLY A. FRANKLIN, and LINDA M. GAUDETTE, *Administrative Patent Judges*.

TIMM, *Administrative Patent Judge.*

DECISION ON APPEAL

I. STATEMENT OF THE CASE

Appellant appeals under 35 U.S.C. § 134(a) from the Examiner's decision rejecting claims 1-6, 9-12, 14-21, and 41. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

The invention relates to a balloon-expandable medical stent. Claims 1 and 41 are illustrative:

1. A balloon-expandable medical stent, comprising: a generally tubular body including an alloy having Ti at about 20 weight percent or more and at least one of Zr, Ta, or Mo, wherein the alloy includes 20 weight percent or greater of Zr, Tz, Mo or a combination thereof, with the proviso that the alloy includes at least about 3 weight percent of Mo, the alloy having a yield strength of about 45 ksi or more, a magnetic susceptibility of about +1 or less, and a mass absorption coefficient of about 1.9 cm^2/g or more.

41. A balloon-expandable medical stent, comprising: a generally tubular body including an alloy having about 20 weight percent or more of Ti and about 40 weight percent or more of Ta, the alloy having a yield strength of about 45 ksi or more, a magnetic susceptibility of about +1 or less, and a mass absorption coefficient of about 1.9 cm_2/g or more.

The Examiner rejects claims 1-6, 11, 12, 14, 15, 18, 19, and 41 under 35 U.S.C. § 103(a) as unpatentable over Fischell (US 5,643,312, issued Jul. 1, 1997) in view of Steinemann (US 4,040,129, issued Aug. 9, 1977). To reject claim 20, the Examiner adds Scott (US 5,383,928, issued Jan. 24, 1995). To reject claim 21, the Examiner adds Wiktor (US 5,653,727, issued Aug. 5, 1997).

The Examiner rejects claims 1-6, 11, 12, 14, 15, 19, and 41 under 35 U.S.C. § 103(a) as unpatentable over Lau (US 5,728,158, issued Mar. 17, 1998) in view of Lenning (US 3,161,503, issued Dec. 15, 1964). To reject claims 16-18, the Examiner adds ASM Handbook (ASM Int'l Handbook Committee, ASM Int'l, 2 ASM Int'l Handbook 588 (1990)). To reject claim 20, the Examiner adds Scott. To reject claim 21, the Examiner adds Wiktor.

Appellant does not argue any claim apart from the others. In accordance with 37 C.F.R. § 41.37(c)(1)(vii), we select claim 1 as representative for deciding the issues on appeal.

II. DISPOSITIVE ISSUES

A. Has Appellant established that the Examiner reversibly erred in concluding that it would have been obvious to form a stent such as that taught by Fischell from the alloy of Steinemann?

B. Has Appellant established that the Examiner reversibly erred in concluding that it would have been obvious to form the stent of Lau using the alloy of Lenning?

III. FINDINGS OF FACT

According to Fischell, stents have been used to maintain patency of arteries and other vessels of the human body (Fischell, col. 1, ll. 11-14). The ideal arterial stent minimizes wire size to reduce thrombosis and has sufficient hoop strength to resist the elastic recoil exerted by the vessel (Fischell, col. 1, ll. 25-18). Fischell optimizes hoop strength by forming a stent from a combination of wires (longitudinals 4T, 4B, 4L, and 4R) and spaced apart rings (2) (Fischell, col. 1, ll. 38-49; col. 2, ll. 39-45; Figs. 1 and 2).

Fischell discloses that, typically, the rings and longitudinals are made of the same material (Fischell, col. 3, ll. 50-51). According to Fischell, "[t]ypical metals used for such a stent would be stainless steel, tantulum [sic, tantalum], titanium, or a shape memory metal such as Nitinol." (Fischell, col. 3, ll. 51-53.)

Fischell further discloses forming the end rings from a different material than the inner rings. For instance, the end rings may be formed

using a radiopaque metal such as tantalum or gold that could be tracked fluoroscopically while the inner rings may be formed from a less dense material (Fischell. col. 4, ll. 5-11). Fischell exemplifies a stent with titanium-plated gold end rings and titanium or titanium alloy inner rings and longitudinals (Fischell, col. 4, ll. 11-19).

Titanium is known to be a comparatively non-thrombogenic metal while tantalum is known to provide an improved fluoroscopic image (Fischell, col. 4, ll. 5-19).

Steinemann describes titanium alloys as implants for surgery having tissue compatibility, corrosion resistance, and high strength (Steinemann, col. 3, l. 47 to col. 4, l. 29). Steinemann indicates that the alloys are useful in a number of different types of implants including bone screws and plates, prosthetic devices (hip, knee, skull), and dental devices (Steinemann, col. 4, l. 60-col. 5, l. 8).

According to Steinemann, implants must withstand corrosion within the living system and avoid any chemical interaction in vivo which would result in a toxic reaction harmful to the living subject (Steinemann, col. 4, ll. 51-59). Steinemann discloses that while there are, in theory, some 50 metallic elements that can be alloyed with titanium (Ti) and zirconium (Zr), based on in vivo and in vitro studies on corrosion rate, only 7 of the possible alloying elements are effective and safe and recommended for use (Ti, Zr, Nb, Ta, Cr, Mo, and Al) (Steinemann, col. 3, ll. 47-58 and col. 5, ll. 49-64).

Lau is directed to a stent (Lau, Title). Lau explains that the stent must be stiff and stable enough radially to maintain the patency of a vessel such as an artery when implanted (Lau, col. 1. ll. 55-60). The tubing used to form the stent may be formed of "suitable biocompatible material such as stainless

steel, titanium, tantalum, superelastic NiTi alloys and even high strength thermoplastic polymers." (Lau, col. 7, ll. 5-7).

Lenning is directed to corrosion resistant alloys (Lenning, col. 1, ll. 9-12). Lenning explains that alloys of titanium and tantalum are substantially less costly than pure tantalum (Lenning, col. 1, ll. 17-21). Lenning further discloses that the addition of a beta stabilizer (V, Mo, Cr, Fe, Mn) allows the alloy to retain ductility to temperatures up to about 800 °F (Lenning, col. 2, ll. 20-29). Embrittlement (loss of ductility) can lead to catastrophic disintegration and is a function of both temperature and time (Lenning, col. 1, ll. 28-33). Even slightly elevated temperatures during a long useful life can produce undesirable embrittlement (Lenning, col. 1, ll. 28-41). The inclusion of the beta stabilizing element further increases yield and tensile strength, allowing the use of thinner and lighter members while retaining strength (Lenning, col. 10, ll. 1-6).

Lenning discloses that the alloys "will be found useful for many applications where corrosion resisting characteristics approaching those of pure tantalum are required." (Lenning, col. 10, ll. 19-21.) Lenning exemplifies uses such as structural or lining materials in autoclaves, and similar relatively high temperature and pressure equipment (Lenning, col. 9, ll. 54-63).

IV. PRINCIPLES OF LAW

"The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007).

V. ANALYSIS

Fischell in view of Steinemann

Weighing the evidence cited by Appellant and the Examiner, we determine that the evidence supports the Examiner's finding of a reason to use the alloy of Steinemann in the stent of Fischell.

Fischell provides evidence that it was known in the art to form stents from tantalum, titanium, and alloys of titanium. Fischell also provides evidence that both tantalum and titanium were known to be biocompatible, a property required in stents. Moreover, Fischell indicates that tantalum is radiopaque, a property desirable when the stent needs to be tracked fluoroscopically. Using either titanium, tantalum or an alloy mixture of the two would have been obvious to one of ordinary skill in the art as both metals were known to be useful in stents. *See, e.g., In re Castner*, 518 F.2d 1234, 1238-39 (CCPA 1975)(one of ordinary skill in the art would have been led to combine known additives for their art recognized functions); *see also In re Kerkhoven*, 626 F.2d 846, 850 (CCPA 1980)(it is prima facie obvious to combine two different materials useful for the same purpose to form a third material which is to be used for the very same purpose).

Appellant does not dispute that Fischell in combination with Steinemann teaches or suggests all of the limitations of the rejected claims. Rather, Appellant contends that a person of ordinary skill in the field of stent design would not have found any reason to use any alloy disclosed by Steinemann in the stent of Fischell, and that the Examiner's reason for making the combination is flawed (Br. 7-9). However, Appellant's arguments neglect the fact that Steinemann discusses specific alloys having corrosion resistance which makes them safe, effective, and recommended for

implantation in the body. The alloys disclosed by Steinemann are alloys of titanium. Fischell discloses using titanium alloys in a stent for implanting in the body. Using the known alloys of titanium disclosed in Steinemann for their known properties to obtain the predictable result of obtaining a stent that is safe and effective for implantation in the body supports a conclusion of obviousness.

Appellant has not established that the Examiner reversibly erred in concluding that it would have been obvious to form a stent such as that taught by Fischell from the alloy of Steinemann.

With respect to the further rejections of claims 20 and 21, in which the Examiner added further evidence directed to additional limitations in these dependent claims, Appellant relies upon the same contentions addressed above. For the reasons above, we determine that Appellant has not established that the Examiner reversibly erred in rejecting claims 20 and 21.

Lau in view of Lenning

The weight of the evidence also supports the Examiner's finding of a reason to use the alloy of Lenning in the stent of Lau.

Lau suggests using suitable biocompatible materials such as either titanium or tantalum to form a stent. As we pointed out above, when a reference teaches using either of two materials, using a mixture of the two, such as an alloy of titanium and tantalum, for the very same purpose would have been obvious to one of ordinary skill in the art. *Castner*, 518 F.2d at 1238-39; *Kerkhoven*, 626 F.2d at 850.

While Lenning is not specifically directed to biocompatible materials for stents, this reference provides evidence of the known properties of alloys of titanium and tantalum and how beta stabilizers such as molybdenum (Mo)

affect those properties. Using the known alloys described in Lenning for their known properties to obtain a stent with those properties would have been obvious to one of ordinary skill in the art in the absence of secondary evidence such as unexpected results.

Appellant has not established that the Examiner reversibly erred in concluding that it would have been obvious to form the stent of Lau using the alloy of Lenning.[1]

With respect to the further rejections of claims 16-18, 20, and 21, in which the Examiner added further evidence directed to additional limitations in these dependent claims, Appellant relies upon the same contentions addressed above. For the reasons above, we determine that Appellant has not established that the Examiner reversibly erred in rejecting claims 16-18, 20 and 21.

VI. CONCLUSION

Appellant has limited the scope of the arguments to the above issues and does not further contest the Examiner's rejection of the claims.[2] Therefore, we sustain all of the rejections of the Examiner.

VII. DECISION

The decision of the Examiner is affirmed.

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[1] Appellant contends that the Examiner mischaracterized the disclosure of Lau (Br. 5-6). We determine that, based on our findings reproduced above, any mischaracterizations by the Examiner did not amount to reversible error.

[2] Only those arguments actually made by Appellant have been considered in this decision. Arguments which Appellant could have made but chose not to make have not been considered and are deemed to be waived. *See* 37 C.F.R. § 41.37(c)(1)(vii) (2008).

VIII. TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED

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